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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,535	08/29/2001	James E. Stein	01997/515001	7176

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CLARK & ELBING LLP
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BOSTON, MA 02110

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942535

Applica.

Stein et al

Examiner

Nuff

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/29/01
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-20 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The proposed drawing correction, filed on 8/29/01 is ☒ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 files 6/1/02
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

The preliminary amendment of 1/17/02 amended the specification. In line 1 of the insertion to page 1 disclosing related applications, this application is stated to be a divisional of 08/345,217. However, in lines 6 and 12 of the insertion, 08/345,217 is recited again, and the relationship of 08/345,217 in lines 6 and 12 to another application is unclear.

claims in the application are 1-20.

Claim Rejections - 35 USC § 103

Claims 1-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Vacanti et al (5,041,138) in view of Yannas et al (4,505,266).

The claims are drawn to a scaffold system which is seeded after implantation *in vivo*. The scaffold is porous and three-dimensional having interconnected pores of between approximately 100 and 300 microns in diameter with sufficient surface area to produce vascularized organ tissue *in vivo*. The scaffold is resistant to compression to maintain the pore size diameter after the scaffold is implanted, and is in combination with a means for introducing parenchymal cells into the scaffold following implantation.

Vacanti et al disclose a fibrous scaffold in which cells can be seeded and the scaffold implanted to form new tissue. The scaffold is designed to provide adequate nutrient and gas exchange to cells.

Yannas et al disclose a fibrous lattice in which cells may be seeded after the lattice has been applied to a wound bed and become vascularized (col 19, lines 15-37). Various means of seeding the lattice with cells such as by using a syringe or pipette (col 9, lines 36-62) are disclosed.

It would have been obvious to provide in combination with the fibrous matrix of Vacanti et al a means such as a syringe or catheter or channels in the matrix for introducing cells after implantation to allow the matrix to become vascularized before seeding with cells to enhance the growth of the cells as suggested by Yannas et al seeding cells into an implanted and vascularized lattice to enhance cell growth. Yannas et al disclose that one advantage of using a syringe is that it can be used to penetrate without removing a covering (col 9, lines 52-55). The scaffold of Vacanti et al inherently has a pore size within the claimed range since it provides adequate diffusion of nutrients. The matrix of Vacanti et al also inherently has sufficient resistance to compression to maintain the pore size after implanting to allow diffusion of sufficient nutrients for cell growth. If the pore size is not maintained after implanting, the growth of cells seeded in the matrix will be inhibited. It is clear that Vacanti et al intend the matrix to have adequate pore size after implanting to provide uninhibited cell growth. Additionally, the matrix of Vacanti et al can be rigid (col 6, line 62), and a rigid matrix can obviously resist compression. Vascularization occurs in the fibrous lattice of Vacanti et al. For example, see col 5, line 55; col 6, line 60; and col 9, line 63. When blood vessels are required for cell growth, it would have been expected that allowing blood vessels to grow before cells are added to the scaffold would be of benefit for the same reason that Yannas et al found that allowing blood vessel formation before seeding with cells to be beneficial. When blood vessels are needed to supply nutrients to cells, having the vessels present when the

cells are seeded will obviously result in better initial growth of the cells.

Claim Rejections - 35 USC § 103

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being obvious
5 over Vacanti et al (5,567,612), (5,804,178), (5,759,830), (5,736,372),
(5,770,417) or (5,770,193) in view of Yannas et al (4,505,266).

Each Vacanti et al patent has a common inventor with the instant
application. Based upon the earlier effective U.S. filing date of the
reference, it constitutes prior art only under 35 U.S.C. 102(e). This
10 rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing
under 37 CFR 1.132 that any invention disclosed but not claimed in the
reference was derived from the inventor of this application and is thus
not an invention "by another"; (2) a showing of a date of invention for
the claimed subject matter of the application which corresponds to
15 subject matter disclosed but not claimed in the reference, prior to the
effective U.S. filing date of the reference under 37 CFR 1.131; or (3)
an oath or declaration under 37 CFR 1.130 stating that the application
and reference are currently owned by the same party and that the inventor
named in the application is the prior inventor under 35 U.S.C. 104,
20 together with a terminal disclaimer in accordance with 37 CFR 1.321(c).
For applications filed on or after November 29, 1999, this rejection
might also be overcome by showing that the subject matter of the
reference and the claimed invention were, at the time the invention was
made, owned by the same person or subject to an obligation of assignment
25 to the same person. See MPEP § 706.02(1)(1) and § 706.02(1)(2).

It would have been obvious to implant the scaffold of each Vacanti et al patent, and allow the matrix to become vascularized before seeding with cells to enhance the growth of the cells as suggested by Yannas et al seeding cells into an implanted and vascularized lattice to enhance cell growth. Providing the scaffold of each Vacanti et al patent with a means such as a syringe or catheter or channels in the scaffold for introducing cells would have been obvious to facilitate the introduction of cells after implanting the scaffold as suggested by Yannas et al.

Claim Rejections - 35 USC § 103

Claims 1-20 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/633,918 in view of Yannas et al (4,505,266). The copending application has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

In view of Yannas et al, it would have been obvious to first implant and vascularize the scaffold of the copending application, and thereafter seed cells into the scaffold to enhance cell growth. Providing the scaffold of the copending application with a means such as a syringe or catheter or channels in the scaffold for introducing cells would have been obvious to facilitate the introduction of cells after implanting the scaffold as suggested by Yannas et al.

The copending applications have an effective filing date prior to the filing date of parent application Serial No. 07/785,021.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(1)(1) and § 706.02(1)(2).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based

been obvious to facilitate the introduction of cells after implanting the scaffold as suggested by Yannas et al.

Double Patenting

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,309,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed system containing a scaffold in combination with a means for introducing cells into the scaffold would have been obvious from the method of the claims of the patent that require in the method a system as presently claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.


The fax phone number is (703) 872-9306 before final rejection or (703) 872-9307 after final rejection.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651

DMN
12/18/02